

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019651/S005

CHEMISTRY REVIEW(S)

McKee

CHEMIST'S REVIEW 1		1. Organization: HFD-180		2. NDA Number: 19-651	
3. Name and Address of Applicant (City & State): Procter & Gamble Pharmaceuticals, Inc. 11450 Grooms Road Cincinnati, OH 45242				4. AF Number: MAY - 1 1997	
				5. Supplement(s)	
6. Name of Drug: Asacol®		7. Nonproprietary Name: mesalamine		Numbers	Dates
				SE1-005	June 4, 1996
8. Supplement Provides for: a new indication (maintenance of remission of ulcerative colitis) and an increased dosing regimen of 2-4 tablets per day.				9. Amendments and Other (Reports, etc.) Dates:	
				BC July 29, 1996 BL.. Jan 27, 1997 BC Mar 10, 1997 BC Apr 10, 1997	
10. Pharmacological Category: treatment of ulcerative colitis		11. How Dispensed: RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. Related IND/NDA/DMF(s): . . .	
13. Dosage Form: delayed-release tablets		14. Potency: 400 mg			
15. Chemical Name and Structure: See USP 23				16. Records and Reports:	
				Current Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
				Reviewed Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
17. Comments:					
<p>cc: NDA 19-651/SE1-005 HFD-180/Div File HFD-181/CSO HFD-180/SFredd HFD-180/AShaw R/D init: EDuffy/4-29-97 ABS/dob F/T 4-30-97/WP: c:\wpfiles\chem\S\19651005.1AS</p> <p style="text-align: right;"><i>/S/</i> <i>5/1/97</i></p>					
18. Conclusions and Recommendations: There is no CMC information provided in this supplement. A FONSI has been prepared and the supplement may be approved.					
9. Reviewer					
Name: Arthur B. Shaw, Ph. D.		Signature <i>/S/</i>		Date Completed: 4/30/97 April 24, 1997	